


TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



**Certificate**  
 No. Q5 104849 0001 Rev. 00

**Holder of Certificate:** **TRIPLEX INTERNATIONAL BIOSCIENCES CO.,LTD**  
 Unit 101, 201, and 301, No. 2041  
 Unit 101, 201, and 501, No. 2045, Xizhou Road  
 Tongan District  
 361100 Xiamen  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In-vitro Diagnostic Kit for Fertility Diagnosis, In-vitro Diagnostic Kit for Tumor marker, In-vitro Diagnostic Kit for Infectious Diseases, Nucleic Acid Extraction Reagent, Staining Solution and Supporting Instruments**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** GZ1941401  
**Valid from:** 2020-04-02  
**Valid until:** 2023-04-01

**Date,** 2020-04-02

  
 Christoph Dicks  
 Head of Certification/Notified Body

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Product Service

# Certificate

No. Q5 104849 0001 Rev. 00

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):** TRIPLEX INTERNATIONAL BIOSCIENCES CO.,LTD  
 Unit 101, 201, and 301, No. 2041, Unit 101, 201, and 501, No. 2045,  
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